REMARKS

In response to the office action of February 19, 2009, Applicants have amended claims 4, 5, 7-8, and canceled claims 2-3, and 6, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of the presently amended claims is respectfully requested.

Claims 2-4 and 8 have been rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claim 11 of U.S. Patent No. 7, 169,791 to Breitenstein et al. The examiner is of the opinion that "leukaemia is a type of vascular disorder". It is respectfully submitted that vascular disease affects the vascular system. The term "vascular" relates to the blood vessels of the body, such as arteries, veins and capillaries. *See* Exhibit A. The term "leukemia" relates to cancer of the blood cells. *See* Exhibit B. Disorders involving blood vessels (i.e. vascular disorders) are distinct from cancer of the blood cells (leukemia). Moreover, claims 4 and 8 have been amended to recite neurological and vascular disorders related to beta-amyloid generation and/or aggregation selected from Alzheimer's disease, Down's Syndrome, memory and cognitive impairment, dementia, amyloid neuropathies, brain inflammation, nerve and brain trauma, vascular amyloidosis, and cerebral hemorrhage with amyloidosis. Since presently pending claims 4 and 8 are distinct from claim 11 of U.S. Pat. No. 7,169,791, the double patenting rejection should be withdrawn.

Claims 2-8 have been rejected as allegedly directed to non-enabled subject matter. The position of the Examiner is that treatment of all neurological and vascular disorders related to beta-amyloid generation by administering the compounds of formula I of the claims is not enabled by the specification. Further, the Examiner has asserted on page 8 of the office action that the specification is only enabling for some compounds encompassed by formula I, namely, 4-Methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide.

As discussed above, claims 4 and 8 have been amended to recite neurological and vascular disorders related to beta-amyloid generation and/or aggregation selected from Alzheimer's disease, Down's Syndrome, memory and cognitive impairment, dementia, amyloid neuropathies, brain inflammation, nerve and brain trauma, vascular amyloidosis, and cerebral hemorrhage with amyloidosis. In addition, claims 4 and 8 have been limited to 4-Methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide or a pharmaceutically acceptable salt thereof. Applicants reserve the right to file one or more

continuation applications directed to the subject of the canceled claims or deleted from the presently pending claims.

In the examples, the compound of example 1, namely 4-Methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide, in example 2 demonstrates a clear reduction of Abeta secretion in the medium of HEK/APPswe cell cultures at concentrations below 10 microM, without having any effect on cellular viability.
The fact that the active compound as tested in the examples has an effect on Abeta-secretion in *all* the human cell models as tested, given the information on the ATP-dependent context of the disease as described in WO 03/057165 A2, demonstrates that as of the filing date of the present application, the presently amended claims were enabled by the specification. Withdrawal of the rejection of claims 2-8 as applied to presently pending claims 4, 5, and 7-8 is therefore respectfully requested.

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, as allegedly lacking clarity, because of the term "inhibitor" that has no basis. Claim 4 as presently amended no longer recites "inhibitor." Withdrawal of the rejection of claim 4 under 35 U.S.C. §112, second paragraph, is therefore warranted.

Claims 2-8 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over over Netzer et al. (WO 03/057165 A2). Netzer et al. has been cited for allegedly teaching methods and compositions for treating amyloid-ß-related disorders such as Alzheimer's disease via administration of compounds that modulate, e.g., inhibit, ATP-dependent enzymatic activity such as Y-secretase activity (page 3, lines 28-31). In one embodiment, the enzyme activity is a kinase activity. The tyrosine kinase may include Abl kinase, BCR-Abl kinase, ARG kinase, src kinase, c-kit or platelet-derived growth factor receptor. In another embodiment, the kinase is a serine/threonine kinase, a carbohydrate kinase or a lipid kinase.

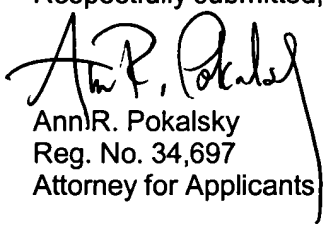
The Examiner readily admits that Netzer et al. does not specifically teach 4-Methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide. However, according to the Examiner, said compound is encompassed by the formula of figure 1 in claim 79 when R_1=H, R_2=heteroaryl; R_3=H; R4=$(C=O)_rO_s(C_1\text{-}C_{10})$alkyl wherein r and s are 0; R_5=$(C=O)_rO_s$heteroaryl wherein r=1 and s=0.

Applicants respectfully traverse the rejection for the following reasons. The formula of figure 1 as recited in claim 79 of Netzer et al. encompasses a myriad of possible compounds. Yet there is nothing in Netzer et al., which would motivate or suggest to one skilled in the art, to

select the specific moieties as the Examiner has done *post facto* to arrive at the presently claimed compound. It is well settled that the disclosure of a large number of possible components does not render obvious the selection of a single compound from among the many, particularly when there is nothing within the four corners of the reference to suggest such a selection. *See In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). Since there is nothing within the four corners of Netzer et al. to suggest the selection of the specific components to arrive at 4-Methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide, the presently amended claims are not obvious. Withdrawal of the rejection of claims 2-8 under 35 U.S.C. §103(a), as applies to claims 4-5, and 7-8 is therefore warranted.

In view of the amendments to the claims, and the foregoing remarks, the present application is believed to be in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Ann R. Pokalsky
Reg. No. 34,697
Attorney for Applicants

DILWORTH & BARRESE
1000 Woodbury Road, Suite 405
Woodbury, New York 11797
ARP/ml

Exhibit A

close window

MedicineNet.com
We Bring Doctors' Knowledge to You

Source: http://www.medterms.com
MedTerms is the Medical Dictionary of MedicineNet.com

Definition of Vascular

Vascular: Relating to the blood vessels of the body. The blood vessels of the body, as a group, are referred to as the vascular system.

The blood vessels are composed of arteries, veins and capillaries -- arteries that pass oxygen-rich blood to the tissues of the body; veins which return oxygen-depleted blood from the tissues to the lungs for oxygen; and the capillaries that are the tiniest vessels and are between the arteries and veins.

Last Editorial Review: 12/14/1999

Search All of MedicineNet For:
Vascular Search search help

Exhibit B

close window

MedicineNet.com
We Bring Doctors' Knowledge to You

Source: http://www.medterms.com
MedTerms is the Medical Dictionary of MedicineNet.com

Start here **Our Leukemia Main Article provides a comprehensive look at the who, what, when and how of Leukemia**

Definition of Leukemia

Leukemia: Cancer of the blood cells. The growth and development of the blood cells are abnormal. Strictly speaking, leukemia should refer only to cancer of the white blood cells (the leukocytes) but in practice it can apply to malignancy of any cellular element in the blood or bone marrow, as in red cell leukemia (erythroleukemia).

Leukemia is a type of cancer. Cancer is a group of more than 100 diseases that have two important things in common. One is that certain cells in the body become abnormal. Another is that the body keeps producing large numbers of these abnormal cells.

Each year, nearly 27,000 adults and more than 2,000 children in the United States learn that they have leukemia.

Last Editorial Review: 3/26/1998 2:27:00 PM

Common Misspellings: leukaemia, lukemeya, lukemia, luekemia, leukimia

Search All of MedicineNet For:
Leukemia Search search help